

INITIAL REMARKS

Applicants filed a Response to the July 30, 2006 Office Action on November 30, 2006. It has since come to the undersigned's attention that an incorrect description of the structures taught by the present application and Mancini was included in the Response. Accordingly, the present response is being filed to correct the record, and should be considered to replace the November 30, 2006 Response. For clarity, the remainder of the November 30, 2006 Response is set forth below in its entirety.

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REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks, which place the application in condition for allowance. The Examiner is thanked for the withdrawal of the previous rejection under 35 U.S.C. §112.

I. INFORMATION DISCLOSURE STATEMENT

The Office Action stated that the Information Disclosure Statement filed September 23, 2005 was improper because a US patent was listed in the incorrect section. Applicants respectfully submit that this oversight has been previously corrected.

The September 23, 2005 Information Disclosure Statement listed two references: US 5,532,289 and JP 10-124,533. The March 15, 2006 Office Action included a copy of the PTO-1449 submitted with the September 23, 2005 Information Disclosure Statement, which indicated that JP 10-124,533 had been considered, and on which form the entry listing US 5,532,289 had been crossed off.

Applicants submitted an Information Disclosure Statement on July 10, 2006, which properly listed US 5,532,289. Applicants received an initialed copy of the July 10, 2006 PTO-1149 form, indicating that US 5,532,289 had been considered, as an attachment to the July 31, 2006 Final Office Action.

Accordingly, as both references initially included on the September 23, 2005 Information Disclosure Statement have now been considered, Applicants verily believe that no further correction to the Information Disclosure Statement is necessary.

II. THE ART REJECTIONS ARE OVERCOME

Claim 1-6 and 9-22 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Mancini *et al.* (US 4,056,496) in view of Mitra *et al.* (US 5,212,015). Applicants respectfully traverse.

The Office Action states that "Although Mitra ... and Mancini ... have different purposes for their disclosed deketalization processes, both references involve deketalizing organic compounds," and that one of skill in the art would "appreciate the high purity of compound obtained with Amberlyst-15 is employed." Office Action at 3. The Office Action concludes that as a result, "it would have been obvious to one of ordinary skill in the art to incorporate the immobilized acid teachings of Mitra *et al.* into [the] deketalization process of Mancini *et al.*" Office Action at 3-4. Applicants respectfully disagree.

The Examiner is respectfully reminded that for a Section 103 rejection to be proper, there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings to arrive at the claimed invention. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, the Examiner is respectfully reminded that "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification."

Also, the Examiner is additionally respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure.** *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the Examiner is also respectfully reminded that MPEP 2143.01 mandates that for a Section 103 rejection, there must be some suggestion or motivation to modify reference teachings, and, that MPEP 2143.02 further mandates that for a section 103 rejection, there must be a reasonable expectation of success.

Applicants respectfully submit that neither of the references relied on in the Office Action provide any teaching or suggestion of the present invention, either individually or in combination. Furthermore, neither of the cited references provide any motivation to combine or any expectation of success.

The present claims are directed towards a process for the preparation of a polymerizable composition comprising a cross-linker and a polymerizable monomer of formula I, comprising the steps of: (i) contacting a compound of formula II, with an immobilized acid, and (ii) neutralizing the product of step (i) such that the cross-linker is formed. As is stated in the present application (for example at page 3, line 1 to page 4, line 19), a significant disadvantage of the prior art processes is that, when producing a polymerizable monomer, it is difficult to control the level of crosslinker in the polymerizable monomer produced.

Inability to control the level of crosslinker in the produced polymerizable monomer is a significant disadvantage because of at least two reasons. First, if the level of crosslinker is not reliably known, then it is difficult to determine the required amount of additional crosslinker to be added (if any) in the subsequent polymerization of the polymerizable monomer and, hence, it is difficult to control the degree of crosslinking in the polymer produced during the polymerization. Second, if the level of crosslinker in the polymerizable monomer produced is too high, additional and potentially costly purification steps are required to reduce the level of crosslinker in the polymerizable monomer produced to the desired level.

The above problem of controlling the level of crosslinker present in polymerizable monomer compositions is particularly evident in the production of polymerizable monomers containing unsaturation in the acyl moiety (*i.e.* the polymerizable monomers to which the process now claimed in the present application is directed).

The present invention overcomes these significant problems found in the prior art.

Applicants have surprisingly found that, by utilization of the specific process now claimed, high purity polymerizable monomer compositions can be produced wherein the polymerizable monomer contains unsaturation in the acyl moiety, and wherein the level of crosslinking monomer present in such compositions can be controlled. Indeed, utilization of the specific process of the present invention allows polymerizable monomer compositions to be produced having high purity and with a controlled level of crosslinker without the need to carry out additional and potentially costly purification steps.

Therefore, Applicants respectfully submit that the present invention fulfills a long-felt need in the art, which solution was not obvious to those of skill in the art, as evidenced by the fact that Mancini and Mitra were publicly available to those of skill in the art since 1977 and 1993, respectively, more than 22 and 6 years, respectively, prior to the earliest filing date of the present application. If the combination of Mancini and Mitra were obviously a solution to the problems in the art described herein, one would have expected a solution much closer to their publication dates.

Turning to each of the documents individually, in producing the monomers disclosed on lines 35 to 38 of column 3 of Mancini, Mancini discloses that the monomer-containing product obtained by the deketalization process is subjected to purification processes (e.g. solvent extraction/stripping under reduced pressure in Example 1 and solvent extraction and evaporation in Example 2 of Mancini). One of the improvements of the present invention is that such purification processes are not required by the method of the present invention, thereby further demonstrating the differences between Mancini and the present invention.

Indeed, there is no teaching or suggestion in Mancini that polymerizable monomers having the formula (I), as required by the present claims, can be produced by the specific process recited in claim 1. In particular, Mancini fails to teach or suggest that such polymerizable monomers can be produced having a high purity without the need for additional, and potentially costly purification steps.

The Office Action alleges that Mitra corrects the deficiencies of Mancini. Applicants respectfully disagree.

The Office Action refers to Example 21 of Mitra, and has alleged that this Example is such that a skilled person would appreciate that a high purity product can be obtained when Amberlyst 15 is utilized. However, Applicants respectfully assert that as in the case of Mancini, the product obtained in Example 21 of Mitra is later subjected to a purification procedure (i.e. recrystallization) in order to obtain the desired product.

Therefore, it is respectfully submitted that, in contrast to the Office Action's allegation, there is no disclosure or teaching in Mitra that would direct the skilled person to believe that the use of Amberlyst 15 would necessarily lead to a high purity product. Indeed, the process of Mancini requires further purification, as does the process of Mitri, including as to those examples utilizing Amberlyst 15. Accordingly, the combination of Mancini and Mitri cannot be found to

provide a high purity product that would require no further purification as neither reference individually provides for such a product, and there is no teaching or suggestion that the combination of them would do so.

Furthermore, the starting material utilized in Example 21 of Mitra is structurally significantly different when compared to the compounds defined by formula (II) in claim 1. And, the starting material used in Example 21 of Mitra is also structurally significantly different to the materials disclosed in Mancini for producing the compounds having the formula shown on lines 35-38 of column 3 of Mancini. Consequently, one of skill in the art would have no motivation to combine processes for such significantly different compounds.

An additional difference between Mitra and the present invention is that Example 21 of Mitra, which is alleged by the Office Action as being particularly relevant, does not neutralize the product obtained by the deketalization process, a feature that is essential in the process now claimed in claim 1 of the present application.

In view of the significant difference in the nature of the starting material used in Example 21 of Mitra when compared to Mancini, and also the fact that Example 21 of Mitra does not utilize a neutralization step, it is respectfully submitted that a skilled person would not be directed to considering combining the teachings of Mitra with those of Mancini and, in particular; would not be directed to combining the teachings of Mitra and Mancini in such a manner as to arrive at the specific process now claimed in the present application in the expectation that such process would give rise to the stated surprising and unexpected advantages, e.g. a high purity product wherein the level of crosslinker can be controlled.

Applicants also respectfully assert that neither Mancini nor Mitra is concerned with the production of polymerizable monomer compositions having a controlled level of crosslinker; this is further evidence that a skilled person would not, from the disclosure of Mancini and Mitra, be directed to the specific process now claimed in claim 1 of the present application.

Furthermore, Applicants respectfully submit that the neutralization step of the process as claimed results in neutralization of any trace level of acrylic acid or methacrylic acid in the resultant polymerizable composition produced by the reaction of the compound of formula (II) with the immobilized acid. This is important since the presence of acrylic or methacrylic acid in the polymerizable monomer composition, due to the cationic charge on the acid, can be associated with the deposition of undesirable proteins on the surface of contact lenses or

biomedical devices. Although Mancini does disclose a neutralization step, it is only stated to be for the purpose of neutralizing the sulphuric acid and no mention is made as to the neutralization of any acrylic or methacrylic acid. Indeed, Mancini makes no reference to any production of acrylic or methacrylic acid. And, as the relevant portions of Mitra fail to teach or suggest any neutralization step, Mitra fails to remedy this deficiency in Mancini.

Therefore, it is respectfully submitted that the disclosure of Mancini or Mitra, either alone or in combination, is such that a skilled person would not be directed to the specific process now defined in claim 1 of the present application and, in particular, is such that a skilled person would not be directed to the specific process of claim 1 in the expectation of obtaining a high purity product and also enabling control of the level of crosslinker in such product. One of skill in the art would have no motivation or suggestion to combine the references, nor would the application of Mitra to the teachings of Mancini allow one of skill in the art to arrive at the presently claimed invention. Accordingly, the rejection of the claims over the combination of Mancini and Mitra is improper, and must be withdrawn.

Consequently, reconsideration and withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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